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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/554,288 | 02/06/2006 | Mark J. Redmond | 2315-127 | 3148 |
| 6449 7590 04/25/2007 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005 | | | EXAMINER MACAULEY, SHERIDAN R | |
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| SHORTENED STATUTORY PERIOD OF RESPONSE | | NOTIFICATION DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/25/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/554,288

Applicant(s)

REDMOND ET AL.

Examiner

Sheridan R. MacAuley

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1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :Filed on February 26, 2006 and October 25, 2005.

DETAILED ACTION

Claims 1-27 are pending.

Election/Restrictions

Claims 17-27 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 26, 2007.

Claims 1-16 are examined on the merits in this office action.

Specification

1. The use of trademarks such as TRAMFLOC, SURFLOC, AQAUMARK, SUPERFLOC, TERMAMYL, SPEZYME, CELITE and PHAOCOCELL (for example, on pages 15-18 and 25-28) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claim 16 objected to because of the following informalities. It is recommended that the claims be amended as follows: The word "participate" line 6 should be changed to "particulate". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 9, 11, 12 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatti (US Pat. 5,518,710, 1996). Claim 1 recites a method of isolating beta (1-3) beta (1-4) glucan (referred to as beta glucan in this office action) from milled cereal grain or a milled part of the cereal grain comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from about 10% to about 25% weight/weight (w/w) of a C₁-C₄ alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claim 2 further limits claim 1 by reciting the limitation that the alcohol of step (iii) is about 10% to about 20% (w/w) of an alcohol selected from the group consisting of methanol, ethanol and isopropanol. Claim 3 further limits claim 2 by reciting the limitation that the alcohol is ethanol. Claim 4 further limits claim 1 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2

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microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 5 further limits claim 4 by reciting the limitation that the starch material is digested with an enzyme. Claim 6 further limits claim 5 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claim 9 further limits claim 5 by reciting the limitation that the enzyme is an amylase. Claim 11 further limits claim 1 by reciting that the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, and a cultivar of corn. Claim 12 further limits claim 1 by reciting the limitation that the pH of the alkaline solution is from about 9 to about 10. Claim 14 further limits claim 1 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 15 further limits claim 1 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding about 10% to about 25% (w/w) of the C₁-C₄ alcohol to the aqueous solution, and isolating the beta glucan. Claim 16 recites a method of isolating beta glucan from a milled cereal grain or a milled part of the cereal grain, comprising: (i) extracting the milled cereal grain or milled part of a cereal grain with an alkaline solution to produce an extract comprising at least about 0.4 weight % beta glucan; (ii) removing insoluble material and removing particulate material having a particle size of greater than about 0.2 microns from the extract to produce a purified extract, wherein the step of removing particulate material comprises one or

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more steps of adding a flocculant, a coagulant or both a flocculant and a coagulant to said extract to coagulate particulate material having a particle size of greater than about 0.2 microns, and removing the coagulated material from the extract, enzymatically digesting starch material in said extract, and filtering out material having a particle size of greater than about 0.2 microns from the extract to produce a purified extract; (iii) adding about 10% to about 25% (w/w) of a C₁-C₄ alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan.

5. Bhatti teaches a method for extracting beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) from milled cereal grain (including cultivars of barley, oat, wheat, rye, corn, sorghum and millet; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14 (col. 3, lines 22-26), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatti would inherently be larger than 0.2 microns; col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C₁ to C₄ alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatti would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatti discloses the use of cereals and milled cereal grains as starting materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from

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1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatti is produced by the methods claimed in the instant application, the extract produced by Bhatti would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatti teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatti teaches that the pH of the alkaline solution can adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatti teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatti teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9).

6. Therefore, Bhatti anticipates all of the limitations of claims 1-6, 9, 11, 12 and 14-16.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatti in view of Puski et al. (US Pat. 4,830,861, 1989). Claims 1, 4, 5 and 6 have been discussed above. Claim 7 further limits claim 6, which depends from claims 1, 4 and 5, by reciting the limitation that, following the digestion of the starch material, the enzyme is inactivated. Claim 8 further limits claim 7 by reciting the limitation that the enzyme is inactivated by acidifying the neutralized solution.

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11. The teachings of Bhatti have been discussed above. Bhatti does not teach the inactivation of the enzyme, particularly inactivation using an acid.

12. Puski et al. teaches the use of amylase for digestion of starch and inactivation of the enzyme using an acid (col. 16, lines 55-63).

13. As discussed above, a process for extraction of beta glucan from milled cereal grain was known at the time of the invention comprising the steps of using an alkaline solution to produce an extract with at least about 0.4 weight percent beta glucan, removal insoluble and particulate matter of particle size greater than 0.2 microns by adding a flocculant and/or coagulant to coagulate particulate material, digesting the starch material in the extract with an enzyme, filtering out the particulate material having a particle size greater than about 0.2 microns from said extract to produce a purified extract, adding an alcohol to precipitate the beta glucan, and isolating the beta glucan. It was also known in the art at the time of the invention that an enzyme (amylase) could be inactivated in a reaction mixture by acidifying the solution, as taught by Puski et al. The motivation to combine the teachings of Bhatti and Puski et al. is taught by Puski et al, who teaches that the inactivation of amylase in a reaction mixture is desirable (col. 1, lines 55-63). It would therefore have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings discussed above to develop a method for extraction of beta glucan from milled cereal grain using the claimed method comprising the addition of an enzyme for digestion of starch material with a method for denaturing the enzyme in a reaction mixture by acidification.

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14. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings discussed above by denaturing the enzyme in the reaction mixture for the extraction of beta glucan from milled cereal grain because Bhatti teaches that the reaction mixture could be acidified to a pH as low as 2 (col. 3, lines 48-52). Puski et al. teaches that the use of a pH of 3.8 is sufficient to inactivate the amylase in the reaction mixture (col. 16, lines 61-62). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in using a method for inactivation of an enzyme using acidification in a method for extraction of beta glucan from milled cereal grain using the claimed method comprising the addition of an enzyme for digestion of starch material.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatti in view of Novozymes (June 1, 2002, novozymes.com). Claims 1, 4, 5 and 9 have been discussed above. Claim 10 further limits claim 9, which depends from claims 1, 4 and 5, by reciting the limitation that the amylase does not require a calcium cofactor.

16. The teachings of Bhatti have been discussed above. Bhatti does not teach the use of an amylase that does not require a calcium cofactor.

17. Novozymes teaches an amylase, TERMAMYL ULTRA 300 L, that does not require a calcium cofactor (p. 1, paragraph 6).

18. A method for extraction of beta glucan using the claimed conditions comprising the addition of amylase to the reaction mixture was known in the art at the time of the invention, as discussed above. Further, an amylase that does not require the addition

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of a calcium cofactor was known in the art at the time of the invention, as taught by Novozymes. One of ordinary skill in the art would have been motivated to combine the teachings of Bhatti and Novozymes because Bhatti discusses the use of TERMAMYL and the addition of calcium ions for the enhancement of the enzyme (col. 3, lines 60-62). Novozymes discusses an improvement to the TERMAMYL enzyme that makes it more stable in the absence of calcium ions, and that the addition of calcium ions is not always sufficient for maintaining the stability of the enzyme (p. 1, paragraphs 4 and 6). One skilled in the art would therefore have been motivated to use the improved enzyme taught by Novozymes, TERMAMYL ULTRA 300 L, in a method for extraction of beta glucan which uses an TERMAMYL. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above by using an amylase that does not require the addition of a calcium cofactor with a method for the extraction of beta glucan using the claimed conditions comprising the addition of an amylase.

19. One of ordinary skill in the art would have had a reasonable expectation of success in combining the use of an amylase that does not require the addition of a calcium cofactor with a method for the extraction of beta glucan using the claimed conditions because it was known in the art at the time of the invention that TERMAMYL was a compatible enzyme for use the extraction of beta glucan, as taught by Bhatti. Novozymes teach that TERMAMYL ULTRA 300 L is an improved TERMAMYL that functions as an amylase and does not require the addition of a calcium cofactor. Therefore one of ordinary skill in the art would have had a reasonable expectation of

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success in using an amylase that does not require the addition of a calcium cofactor in a method for extraction of beta glucan using the claimed conditions.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatti in view of Potter et al. (US Pat. 6,323,338, 2001). Claim 1 has been discussed above. Claim 13 further limits claim 1 by reciting the limitation that step (i) is carried out over a period of from about 15 to about 45 minutes.

21. The teachings of Bhatti have been discussed above. The alkaline extraction step of Bhatti is carried out for between about 2 and about 25 hours (col. 3, lines 41-42). Bhatti does not teach that the step of extracting the beta glucan with alkaline solution is carried out for about 15 to about 45 minutes.

22. Potter et al. teach a method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours (abstract, col. 5, lines 13-18).

23. A method for the extraction of beta glucan using the claimed reaction conditions was known in the art at the time of the invention, as taught by Bhatti and discussed above. A method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours was also known in the art at the time of the invention, as taught by Potter et al. One would be motivated to combine the teachings of Bhatti and Potter et al. because Potter et al. discuss the need for efficient processes for extraction of beta glucan (col. 2, lines 23-27). One skilled in the art would therefore have been motivated to reduce the time of the alkaline extraction step of the method for

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extraction of beta glucan taught by Bhatti to about 0.5 to about 3 hours, as taught by Potter et al. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to reduce the length of time in the alkaline extraction step of the method taught by Bhatti to develop a method for extraction of beta glucan using the claimed conditions.

24. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Bhatti and Potter et al. to develop a method for extraction of beta glucan using the claimed conditions with a shorter length of time for the alkaline extraction step because it was known in the art at the time of the invention that beta glucans could be extracted from milled cereal grain using an alkaline extraction step that is carried out for about 0.5 to about 3 hours, as taught by Potter et al. Therefore, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in combining the teachings of Bhatti and Potter et al. by developing a method for extraction of beta glucan using the claimed conditions.

25. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jamas et al. (US Pat. 5,817,643, 1998) teaches a method for the extraction of beta glucan comprising ethanol precipitation and filtration steps. Vasanthan et al. (US Pub. 2004/0001907) teaches a method for the extraction of beta glucan comprising the steps of alcohol precipitation and incubation with amylase.

27. The examiner notes that claims 1-16 have not been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13-27 of copending Application No. 10/554290 because, although claims 13-27 of U.S. App. 10/554290 recite a product made by the process of claims 1-16 of the instant application, the claims directed to the product have been determined to be patentably distinct from the claims directed to the process because the examiner required restriction between the product and process claims of the instant application in the office action mailed on January 31, 2007.

Conclusion

No claims are allowed.

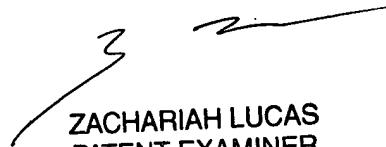
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM



ZACHARIAH LUCAS
PATENT EXAMINER